

AGENDA
CIRCULATORY SYSTEM DEVICES PANEL

April 22, 2005

Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

8:00 – 4:30		510(k) Discussion and Recommendations
8:00 a.m.	Call to Order	William H. Maisel, M.D., M.P.H. Chairperson
8:05 – 8:20 a.m.	FDA Presentation: Condition of Approval Studies: Recent Changes in CDRH Susan Gardner, PhD; Director, Office of Surveillance and Biometrics	
8:20 – 8:35 a.m.	FDA Presentation: Panel update David Buckles, PhD, FACC; Branch Chief, Peripheral Vascular Devices Branch	
8:35 – 9:05 a.m.	*Open Public Session*	
9:05 – 10:05 a.m.	Sponsor Presentation: Cardica Inc. K030434: Cardica™ PAS-Port™ System	
10:05 – 10:20 a.m.	Questions and Answers	
10:20 – 10:35 a.m.	Break	
10:35 – 11:35 a.m.	FDA Presentation	
11:35 – 11:50 a.m.	Questions and Answers	
11:50 – 12:30 p.m.	Open Committee Discussion	
12:30 p.m.	Adjourn – Break for Lunch	
1:30 p.m.	Call to Order	William H. Maisel, M.D., M.P.H.
1:30 – 3:00 p.m.	Open Committee Discussion	
3:00 – 4:00 p.m.	*Open Public Session*	
	FDA Comments	
	Sponsor Comments	
	Recommendations	
	William H. Maisel, M.D., M.P.H.	
4:00 p.m.	Adjourn	

OPEN PUBLIC HEARINGS*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Ms. Wood will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Maisel will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.